4-3-90

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

APR 3 1990

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM:

SUBJECT: ID #90-WI-06 [DEB:#6429] [MRID: n/a] Vinclozolin [RONILAN®]: Section 18 exemption on snap beans in the State of Wisconsin.

FROM: William L.Anthony, Chemist
Special Registration Section II
Dietary Exposure Branch
Health Effects Division [H7509C]

William L. Anthony

THRU: Francis B. Suhre,Section Head
Special Registration section II
Dietary Exposure Branch
Health Effects Division [H7509C]

Francis B Suhre

TO: Rebecca Cool/Libby Pemberton, PM #41
Registration Support Branch
Registration Division [H7505C]
and
Toxicology Branch
Health Effects Division [H7509C]

The State of Wisconsin, Department of Agricultural, Trade & Consumer Protection, requests a Section 18 emergency exemption for use of the active ingredient, vinclozolin [RONILAN®], 3-(3,5-Dichloro-phenyl)-5-ethenyl-5-methyl-2,4-oxazolidinedione to control white mold, Sclerotinia sclerotiorum , on snap beans. Approximately 41,500 acres of the snap beans will be treated with vinclozolin in the State of Wisconsin, under this exemption.

In 1983 and 1985, the State of Washington received Section 18 exemptions for use of vinclozolin on snap beans [Memo: 83-WA-09, E.Zager, 4/20/83] and lima beans [Memo:85-WA-06, W. Anthony, 6/27/85], respectively. In 1984 and 1990, the State of Oregon received two Section 18 exemptions for the use of vinclozolin on snap beans, [Memo: 84-0R-08, M.Loftus, 6/5/84 and 90-OR-08, F. Toghrol 3/21/90)]. In 1989, the State of Wisconsin received a similar Section 18 exemption for snap beans,[Memo: 89-WI-09,F.Toghrol,4/3/89].

RONILAN®-50W [EPA #7969-53] and RONILAN®-FL [EPA #7969-62] contain 50% and 41% of vinclozolin, respectively.

TOLERANCE

Tolerances are established [40 CFR 180.380] for combined residues of the parent vinclozolin [3-(3,5-dichlorophenyl)-5-etheneyl-5-methyl-2,4-oxazolidinedione] and its metabolites containing the 3,5-dichloro-aniline moiety, in or on head lettuce, strawberries, raspberries and kiwi fruit at 10 ppm; stone fruits at 25 ppm; bell peppers at 3.0 ppm; onions (dry bulb) at 1.0 ppm; and grapes at 6.0 ppm. A feed additive tolerance has been established (40 CFR 186.1850) for vinclozolin/on grape pomace (dry) at 42 ppm. Temporary tolerances for residues of vinclozolin at 5.0 ppm in/on dry and succulent beans expired 5/29/85, PP#5F3237/5H5465.

A petition proposing permanent tolerances for residues of vinclozolin on meat, milk, poultry, and eggs is currently under review [PP#9F3750].

A registration standard for vinclozolin has not been issued.

Proposed Use

90-WI-06 calls for application of 1.0 to 1.5 lbs (0.5 to 0.75 lbs ai) RONILAN®-50W/acre or 1.0 to 1.5 pts (0.5 to 0.7 lbs ai) RONILAN®-FL/ acre. A maximum of two applications per season (up to 1.5 lbs. ai/A/season) may be made. Initiate treatment at early to midbloom and repeated 14 days later if needed. A PHI was not advanced. Application may be made with ground equipment using 30 to 50 gallons of water/per acre or by air using five gallons of water/per acre. All applicable directions, restrictions, and precautions on the EPA registered label are to be followed.

Metabolism

No plant or animal metabolism studies were submitted with this request; however, metabolism studies on vinclozolin were previously submitted in connection with PP#5F3237/FAP#5H5465. For purposes of this Section 18, DEB considers the metabolism of vinclozolin in plants and animals to be adequately understood. The residues of concern are vinclozolin and its metabolites containing the 3,5-dichloroaniline moiety.

Analytical

A method for assaying the parent and its metabolites of concern is described in PAM II, Method I. The analysis is via GLC/EC. This method is considered suitable for enforcement purposes.

Residues

No residue studies were submitted with this request. However, residue data on snap beans were previously submitted in connection with PP #5F3237/FAP #5465 and PP #9F3762.

The available data from PP#5F3237/FAP#5465 reflect two applications at a rate of 1.0 lb ai/A each. These data are summarized below:

Rate of Application lbs ai/A (# days between 2 appl.)	PHI days	Residues of vinclozolin PPM snap beans	snap bean forage
1.0 + 1.0 (13)	13	1.5	-------
1.0 + 1.0 (7)	17	0.6	18.2
1.0 + 1.0 (7)	16	0.3	4.2, 4.0
1.0 + 1.0 (14)	14	0.5	4.7
1.0 + 1.0 (14)	14	1.2	9.0
1.0 + 1.0 (10)	15	0.2	--------
1.0 + 1.0 (15)	9	0.6	3.0

Additional residue data submitted in connection with PP#9F3762, reflecting a single application at 1.0 lb ai /A (1X the same rate proposed by (90-OR-08) are summarized below:

Type of Appl /1.0 lb ai/A Location	PHI day	Residue of Vinclozolin/ppm snap bean	snap bean green forage	Dry forage	Cannery Waste
Ground/NC	14	0.6	3.7	8.1	---
Ground/NY	14	0.4	3.5	6.3	0.9
Ground/FL	14	0.5	9.7	17.4	---
Ground/MI	14	0.7	13.5	15.7	---
Ground/CA	14	2.4	50.8	164.0	9.8
Aerial/MI	14	0.6	7.6	7.3	---
Aerial/NY	14	0.8	15.1	32.6	2.5
Irrigate/OR	14	0.9	7.6	21.1	1.7
Irrigate/WI	14	0.7	4.3	14.2	---

Based on these data, DEB concludes that residues of vinclozolin and its metabolites containing the 3,5-dichloroaniline moiety will not exceed 3.0 ppm in/on snap beans; 50.0 ppm in/on green snap beans forage; 164 ppm in/on dry forage; and 10 ppm in cannery waste as a result of this proposed use Section 18.

Meat, Milk, Poultry, and Eggs

Snap beans (seeds and pod) may be fed to cattle (20%), swine (25%) and poultry (15%) of their diet. Beans vines (bean forage) and hay are also used as animal feed items and may reflect 20% to 35% of the diet of dairy cattle. Bean vines and hay are considered to be under the control of the grower and thus subject to label restrictions against feedings.

Grape pomace (dry) may be fed to poultry and cattle at 5% and 30% of their diet respectively. If the diet of cattle consist of 35% bean forage, 20% bean seed and 30% grapes pomace, the maximum vinclozolin dietary burden to cattle would be 30 ppm. Similarly if the diet of poultry consists of 25% snap beans seed, and 5% grape pomace, the maximum vinclozolin dietary burden to poultry would be 3.0 ppm.

The results of a feeding study (PP#5F3237/FAP#5H5465) in which dairy cattle, and poultry were fed 3 ppm and 15 ppm vinclozolin for 28 days are summarized below:

Commodity	Feeing Dose		
	3 ppm	15 ppm	30 ppm
Cattle milk	0.06	0.23	----
cattle fat	0.10	0.63	----
cattle kidney	0.22	1.19	----
cattle liver	0.75	2.89	----
cattle muscle	0.06	0.30	----
poultry eggs	0.10	0.39	0.95
poultry fat	<0.05	0.14	0.17
poultry kidney	0.10	0.39	0.55
poultry liver	0.08	0.58	0.88
poultry muscle	<0.05	0.12	0.18
poultry skin	0.05	0.13	0.19

Based on these data and a potential vinclozolin dietary burden of 30 ppm for cattle and 3.0 ppm vinclozolin for poultry, we conclude that secondary residues of vinclozolin are not likely to exceed 0.5 ppm in milk; 1.0 ppm in cattle fat, 0.5 ppm in muscle, 5.0 ppm in liver, 2.0 ppm in kidney; and 0.1 ppm in poultry eggs, muscle, liver, and kidney as a result of this proposed Section 18.

Conclusions:

1. The metabolism of vinclozolin in plants and animals is adequately understood. The residues of concern are vinclozolin and its metabolites containing the 3,5-dichloroaniline moiety.

2. The GLC analytical method (Method I) described in PAM II is adequate for enforcement purposes. Analytical reference standards of vinclozolin are available from the EPA Repository.

3. Residues of vinclozolin are not expected to exceed 3.0 ppm in/on succulent snap beans, and 50.0 ppm in/on succulent snap beans forages, as a result of this proposed use.

4. Residues of vinclozolin are not expected to exceed 0.5 ppm in milk; 1.0 ppm in cattle fat, and 0.5 ppm in cattle muscle, 5.0 ppm in cattle liver, 2.0 ppm in cattle kidney; and 0.1 ppm in poultry eggs, muscle, liver, and kidney as a result of this proposed Section 18, provided a label restriction against feeding bean "hay" to cattle is in effect.

Recommendations:

TOX considerations permitting, DEB has no objections to this section 18, provided a 14 day PHI and a label restriction against feeding bean "hay" to cattle are in effect. An agreement should be made with the FDA regarding the legal status of treated snap beans (succulent) in commerce.

CC:Reviewer;RF;SF[Vinclozolin];Sec.18file;DRES(Kariya);Circu.;
FOD/PIB; R.Schmitt.
RDI:FBS,3/2/90;EZ,4/2/90.
H7509C: WLA;wla;CM-2;Rm.812;X557-4351;4/3/90.